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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,445	12/16/2005	Gary Ruvkun	00786/436002	1398

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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
11/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/540,445	RUVKUN ET AL.	
	Examiner	Art Unit	
	MARIA B. MARVICH	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-10,12-16,18-23,25-33,37-43 and 50-61* is/are pending in the application.

4a) Of the above claim(s) *3,12-16,18-23,25-33,37-43,50,51,53-57 and 59-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7-10,52 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 7/28/08. Claims 1-4, 7-10, 12-16, 18-23, 25-33, 37-43 and 50-61 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group I and C34G6.6 of in the reply filed on 7/28/08 is acknowledged. Claims 3, 12-16, 18-23, 25-33, 37-43, 50, 51, 53-57 and 59-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/28/08.

Claim Objections

Claims 1 and 2 are objected to because of the following informalities: claim 1 recites in line 1 that a "candidate compound" is to be identified. Actually, a candidate compound is tested to identify a compound that disrupts molting. As such it would be remedial to amend the claims to recite in line 1. --a compound-- and then in line 9 to recite --the compound--. Claim 2 recites in line 1 "said cell expresses a *mlt* nucleic acid". However, for clarity it would be preferable to recite --said *mlt* nucleic acid is--.

As well, claims 1, 2, 52 and 58 are drawn to non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2, 52 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification and claims refer to biological deposits to satisfy the "how to make" requirement, but fails to specify the details of the sequence such that one of skill in the art can produce the recited sequences.

More particularly, claims 2, 52 and 58 are drawn to or encompasses use of a specific sequences have the tag of C34G6.6. As such, this application discloses a sequence that is encompassed by the definitions for biological material set forth in37 C.F.R. 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. 1.801 through 1.809.

C34G6.6 is a marker for a sequence that is continually updated and changed. Applicants, therefore, have referenced the sequence by a tag that may be amended or change through time. However to comply with the written description requirement, applicants should provide the sequence that was available at the time of filing either as a deposit or a sequence listing. Otherwise, it is unclear that the gene of claims 2, 52 and 58 will be readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Therefore, in order for a

deposit to meet all criteria set forth in 37 C.F.R. 1.801 through 1.809, Applicant or Assignee must provide assurance of compliance with provisions of 37 C.F.R. 1.801-1.809 in the form of a declaration or Applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the encoded attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, Applicant is required to submit a verified statement from a person in a position to corroborate the statement that the biological material which had been deposited is the biological material specifically identified in the applicants as filed (37 C.F.R. 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 7-10, 52 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying a compound that disrupts *C. elegans* molting wherein the method comprises contacting a *C. elegans* cell with a compound and measuring C34G6.6 transcript and translation product wherein the compound is a candidate to inhibit molting if the level of C34G6.6 transcript or protein is decreased and a nematicide or insecticide that includes a double-stranded RNA, antisense RNA, or siRNA against C34G6.6, does not reasonably provide enablement for any other embodiment. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and In *re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a method of identifying a compound that disrupts Ecdysozoan molting wherein the method comprises contacting *any* cell with a compound and measuring the expression of a nucleic acid or an ortholog wherein the compound is a candidate to inhibit molting in the cell if there is any alteration in the nucleic acid. As well, the claims are drawn to a nematicide or insecticide that includes a portion of C34G6.6 or an ortholog thereof.

The MPEP teaches, "However, claims reading on significant numbers of inoperative embodiments would render claims non-enabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. Atlas Powder Co. v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971). (see MPEP 2164.08(b). In this case, the scope of the invention is extremely broad which leads to a number of unpredictable elements. First, the target cell is any cell so long as the cell comprises C34G6.6 or an ortholog. This is a broad genus of test cells. Furthermore, the test compound is

administered to this generic cell and *any* alteration in expression meant to identify a compound that disrupts molting in any Ecdysozoan. Furthermore, the method as stated does not distinguish from a compound that will alter the level of expression from the promoter of C34G6.6. As well, an alteration encompasses an increase in C34G6.6 transcript or protein, for which it is not clear that either will identify an inhibitor of molting. C34G6.6 is a gene found in *C. elegans*. Using this gene it is not clear that the results can be extrapolated to the genus of Ecdysozoan. Ewer et al teaches that not only is the process of molting complex and intricately interwoven steps but also that nematodes differ significantly from arthropods and yet both are in the same family (see 1696, col 1, past ¶ and page 1697, col 2, last ¶).

Secondly applicants recite a broad genus of sequences as well as portions of sequences for use in the method of screening as well as part of an insecticide or nematicide. Specifically, by recitation of an ortholog, applicants recite a genus of genes that are not described in the specification. Applicants only disclose C34G6.6 and not its orthologs. Again it is not clear that the method can be extrapolated to identify compounds that operate across the genus of Ecdysozoan. As to a nematicide or an insecticide, the only requirement of the claim is that the insecticide or nematicide comprise a portion of C34G6.6 or an ortholog thereof. C34G6.6 is a DNA sequence and it is not clear how such a portion of undetermined structure or function can be used as an insecticide or nematicide.

The invention recites use of a broad group of therapies to lower a level of FHL1. Given the unpredictability of the art, the poorly developed state of the art with regard to predicting the structural/ functional characteristics of antagonists, the lack of adequate working examples and

the lack of guidance provided by applicants, the skilled artisan would have to have conducted undue, unpredictable experimentation to practice the claimed invention.

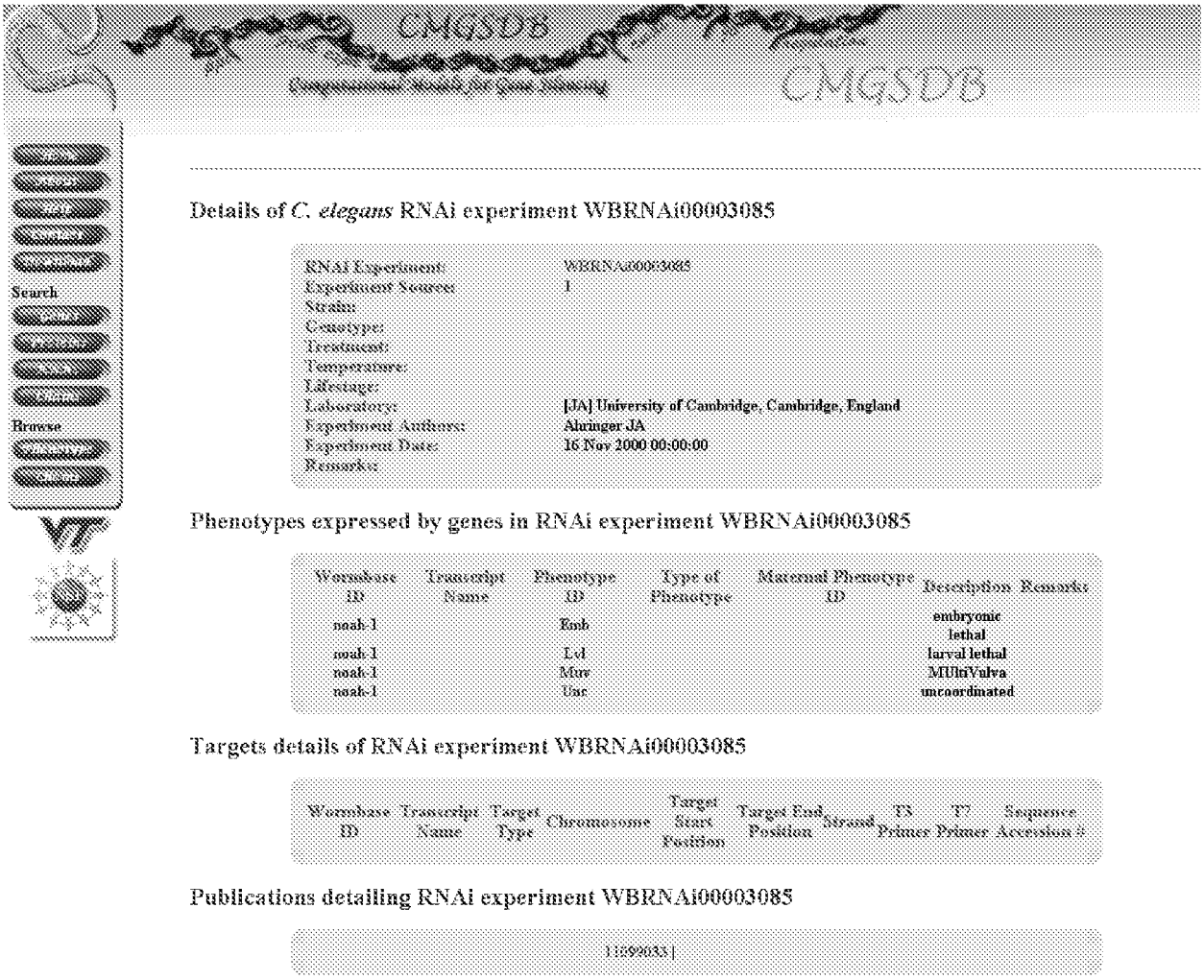
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 7, 8, 10, 52 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Fraser et al (Nature, 2000, Vol 408, pages 325-330) as evidenced by CMGSDB.

Fraser et al teach methods of screening candidate compounds wherein nematodes were treated with the compounds and expression of genes assayed. The compound decreases transcription and hence translation of the gene which is evidenced below includes C34G6.6 or noah-1 as it is otherwise known. Given the phenotype of decreasing expression, one would consider the identified gene to be an appropriate nematicide or insecticide.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 7-10, 52 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser et al (Nature, 2000, Vol 408, pages 325-330) in view of Sluder et al (US 2004/0213771; see entire document).

Applicants claim a method of identifying a candidate compound that disrupts Ecdysozoan molting wherein the method involves contacting a cell with a compound from a chemical library to identify compounds that alter expression of C34G6.6.

The teachings of Fraser et al are described above and are applied as before except Fraser et al do not describe use of a chemical library.

Sluder et al teach methods of identifying compounds that control parasitic nematodes. The method involves analysis of compounds from a chemical library and the effect on molting (see e.g. ¶ 141 and 172). Hence, Sluder et al teach that methods of identifying compounds that function as insecticides or nematicides by altering molting were well known in the art and these methods used chemical libraries as candidate compounds.

KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision Exparte Smith --USPD2d--., slip op. at 20, (BD. Pat. App. & Interfer. June 25, 2007). In the instant case, the combination of Fraser et al and Sluder et al demonstrates an attempt to use known techniques to improve similar methods using skill that was available at the time of filing with well-established methods on well-characterized organisms and cells. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a chemical library as taught by Sluder et al with the method of identifying inhibitors of molting as taught by Fraser et al because Sluder et al teach that it is within the ordinary skill of the art to use chemical libraries to identify

inhibitors of molting and because Fraser et al teach that it is within the ordinary skill of the art to use expression of important molting genes as markers of molting inhibitors and hence nematicides and insecticides. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD

Primary Examiner
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